UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services; and MARGARET HAMBURG, in her official capacity as Commissioner, United States Food and Drug Administration, Defendants.	10 Civ. 5690 (AKH)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITON TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

The United States Food and Drug Administration ("FDA") is engaged in an ongoing regulatory process to develop standards and requirements, known as "monographs," for drugs that are marketed without a prescription (over-the-counter ("OTC")) in the United States. Monographs establish the acceptable ingredients, labeling, and other conditions for each therapeutic class of OTC drugs (*e.g.*, antacids, laxatives, antiperspirants). The development of monographs, known as the OTC Drug Review, affects anywhere from 100,000 to 500,000 different OTC drugs, and requires FDA to consider approximately 800 active ingredients (plus combinations of those ingredients) for approximately 1,400 different ingredient uses. The development of monographs involves extensive notice and comment rulemaking, multi-stage regulatory processes, and requires FDA to resolve a myriad of complex questions of science and

public health policy. Since 1972, FDA has published over 275 proposed and final rules relating to the OTC Drug Review.

Plaintiff Natural Resources Defense Council, Inc. ("NRDC") brought this action to challenge FDA's pace in completing the monograph process for topical antimicrobial drug products, which include antimicrobial handwashes for daily home use as well as preoperative skin preparations and surgical hand scrubs for use by health care professionals. This monograph is one of the largest, most complex, and controversial categories of OTC drugs considered under the OTC Drug Review. The topical antimicrobial drug monograph is comprised of six separate subparts. FDA has finalized three of these subparts, and is working toward finalizing the others.

NRDC focuses its challenge on two active ingredients under consideration in the topical antimicrobial drug monograph—triclosan and triclocarban. FDA is actively engaged in evaluating the use of triclosan and triclocarban in certain antimicrobial products and intends to take action in the near future. However, the timetable that plaintiff proposes—90 days to complete the entire topical antimicrobial drug monograph—is unattainable given significant emerging scientific issues, the current state of the data, and required processes involved in establishing a monograph.

Triclosan and triclocarban are presently the subject of ongoing scientific research, and FDA is actively collaborating with the United States Environmental Protection Agency ("EPA"), the National Institutes of Health ("NIH"), and other federal agencies to develop the scientific understanding it needs to determine whether these substances meet the standard of general recognition of safety and effectiveness. At this time, FDA and other federal agencies agree that insufficient evidence exists to demonstrate that triclosan or triclocarban harm human health.

FDA is mindful of recent concerns expressed by individuals and consumer groups regarding triclosan and triclocarban as it continues to make progress toward developing final monographs for all antimicrobial drug products. There are, however, a number of regulatory steps that FDA must take before finalizing the monograph for topical antimicrobial drug products. Although FDA cannot take final action at this time, FDA expects to issue a proposed rule, or take other regulatory action, on both ingredients as soon as practicable.

Plaintiff's current challenge is not well founded in fact or in law. First, NRDC, an advocacy group, has failed to meet its burden of establishing injury-in-fact and the other required elements of standing to bring this challenge. Second, even if plaintiff had established standing, the undisputed material facts establish that FDA has not unreasonably delayed in completing the portion of OTC Drug Review affecting antimicrobial drug products. Based on either of these independent grounds, judgment should be entered for the Government.

BACKGROUND

I. Statutory and Regulatory Scheme

With the enactment of the Federal Food, Drug, and Cosmetic Act ("Act") in 1938, Congress established the current system of premarketing clearance for drugs in the United States. Pub. L. No. 75-717, 52 Stat. 1040 (1938). "Drugs" are defined by the Act as articles "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" in humans or articles "intended to affect the structure or any function of the body" of humans. 21 U.S.C. § 321(g)(1). In general, the Act, as adopted in 1938 and amended in 1962, prohibits the introduction into interstate commerce of any "new drug" unless FDA has approved a new drug application ("NDA") with respect to that drug. 21 U.S.C. § 355(a). Premarketing clearance under the 1938 Act required the proponent of a "new drug" to establish the drug's safety to

obtain an NDA approval. Pub. L. No. 75-717, 52 Stat. 1040 (1938). The 1962 amendments to the Act changed the definition of "new drug," adding the requirement that a drug be shown to be effective as well as safe before FDA will approve an NDA. Pub. L. No. 87-781, 76 Stat. 780 (1962); *Cutler v. Hayes*, 818 F.2d 879, 883 (D.C. Cir. 1987); *Cutler v. Kennedy*, 475 F. Supp. 838, 840-43 (D.D.C. 1979); Declaration of Charles J. Ganley, M.D. (hereinafter "Ganley Decl.") ¶¶ 5-6.

A drug that is not a "new drug" may be introduced into interstate commerce without prior approval by FDA. 21 U.S.C. § 321(p); 21 U.S.C. § 355(a). A drug is considered a "new drug," in relevant part, if it "is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p). In other words, a drug that is not generally recognized by experts as safe and effective must have an approved NDA before it can be marketed.[1] A drug that is not a new drug—*i.e.*, one that is generally recognized as safe and effective—does not need an approved NDA.

These provisions apply to both prescription drugs and OTC drugs. Prescription drugs are drugs that, because of safety and other concerns, can be dispensed only by or pursuant to the direction of a licensed medical practitioner. 21 U.S.C. § 353(b)(1). An OTC drug is any drug that does not meet the criteria for prescription drugs in § 353(b)(1). OTC drugs play an increasingly vital role in America's health care system by providing easy access to certain drugs that can be used safely without the oversight of a health care practitioner. Ganley Decl. ¶ 5.

[1] FDA uses the acronym "GRAS" to refer to drugs that are generally recognized as safe, and "GRAE" to refer to drugs that are generally recognized as effective. A drug that is generally recognized as both safe and effective is referred to as "GRAS/E" (pronounced "grass gray").

The 1962 Amendments had an immense impact on federal drug regulation. Before 1962, drug manufacturers ordinarily were not required to demonstrate that drugs were effective for their intended uses and, accordingly, manufacturers rarely carried out testing to establish effectiveness. After 1962, FDA was faced with the massive task of evaluating the effectiveness of almost all drugs then marketed in the United States. In 1966, FDA began a retrospective review of the efficacy of over 3,400 drug products marketed in the United States under an NDA between 1938 and 1962 and approved only for safety. 37 Fed. Reg. 85 (Jan. 5, 1972); Ganley Decl. ¶ 6. This review, known as the Drug Efficacy Study Implementation ("DESI"), was done under contract with the National Academy of Science/National Research Council. Ganley Decl. ¶ 6 & n.1; *see also American Pub. Health Ass'n v. Veneman*, 349 F. Supp. 1311, 1313-14 (D.D.C. 1972).[2]

A. The OTC Drug Review

Several years later, once DESI was underway, FDA turned its attention to "the vast OTC market," launching a project that became known as the OTC Drug Review. *Hayes*, 475 F. Supp. at 844; Ganley Decl. ¶ 7. In 1972, FDA issued regulations providing for a comprehensive review of OTC drugs to determine whether they are properly marketable under the GRAS/E exemption and to establish appropriate labeling. *See* 37 Fed. Reg. 9464 (May 11, 1972), codified at 21 C.F.R. § 330.1 *et seq.* In lieu of individually reviewing (as was done in DESI) each of the estimated 100,000 to 500,000 OTC drugs marketed in 1962 in the United States, FDA established rulemaking procedures that would permit review of OTC drugs in classes, designated by therapeutic category (*e.g.*, antacids, laxatives, antiperspirants). *See* 37 Fed. Reg. at 85; Ganley Decl. ¶ 7; *see also Kennedy*, 475 F. Supp. at 857 n.44 (stating that the OTC Drug Review

[2] Most of the drugs reviewed under DESI were prescription drugs, although approximately 420 were OTC. 37 Fed. Reg. at 85; 21 C.F.R. § 330.12(a); Ganley Decl. ¶ 6.

"resulted from the FDA's realization that case-by-case review of the OTC market or de novo judicial proceedings were impossible in light of the large number of OTC drugs and the time consuming nature of such procedures"). FDA's approach avoided protracted litigation on the new drug status of particular drug products, and significantly expedited the overall regulatory process. *See* 37 Fed. Reg. at 86.

The goal of the OTC Drug Review was to develop acceptable "conditions" for each class of OTC drugs as to, *inter alia*, active ingredients, inactive ingredients, doses, labeling (including indications, warnings, and directions for use), and for some classes, final formulation effectiveness testing. 37 Fed. Reg. 9464 (May 11, 1972); 21 C.F.R. §§ 330.1, 330.10; Ganley Decl. ¶ 7. These conditions are published in FDA regulations called "monographs." *See* 21 C.F.R. § 330.10; Ganley Decl. ¶ 7. OTC drugs manufactured in strict conformity with monograph conditions are generally recognized as safe and effective and are labeled appropriately (*i.e.*, not misbranded). *Id.* Because they are generally recognized as safe and effective, drugs adhering to an applicable monograph are not "new drugs" under the Act and do not require premarket approval by FDA. 21 U.S.C. §§ 321(p), 355; Ganley Decl. ¶ 7.

In enacting the 1962 Amendments, Congress did not set forth any procedures or timetable for undertaking a review of OTC drugs. The OTC drug review has proven to be one of the largest, most complex regulatory undertakings by FDA. Ganley Decl. ¶ 8; *see also* R.A. Merrill & P.B. Hutt, Food & Drug Law 801 (3d ed. 2007) ("The OTC Drug Review has been one of the most challenging rulemaking efforts undertaken by any government agency."). It consists of about 88 simultaneous rulemakings in 26 broad categories of OTC drugs and their some 800 significant active ingredients for approximately 1,400 different ingredient uses. Ganley Decl.

¶ 8. The OTC Drug Review affects anywhere from 100,000 to 500,000 OTC drugs marketed in the United States. *Id.*

B. The OTC Drug Review's Four Phases

As structured by FDA, the ongoing OTC Drug Review is proceeding in four distinct phases. *Hayes*, 818 F.2d at 884; 21 C.F.R. § 330.10 *et seq.*; Ganley Decl. ¶¶ 9-21. For each category of OTC drugs, FDA must (1) appoint an advisory review panel of qualified experts to evaluate the safety, effectiveness, and proper labeling for that category of OTC drugs; (2) issue an advance notice of proposed rulemaking ("ANPRM") that publishes or summarizes the advisory review panel's recommendations and conclusions; (3) develop and publish a proposed rule, or "tentative final monograph" ("TFM"); and (4) publish a final rule, or "final monograph," establishing conditions under which a category of OTC drugs are considered generally recognized as safe and effective, and not misbranded. *Id.*

At each stage of the OTC Drug Review, the panel and the Commissioner must apply defined safety, effectiveness, and labeling standards, as set forth in FDA regulations. 21 C.F.R. § 330.10(a)(4); Ganley Decl. ¶ 20. Because each category of OTC drugs has distinct characteristics, FDA's analysis of the applicable standards differs by drug category. Ganley Decl. ¶ 20.

1. Phase I: Panel Review

During the first phase, which began in 1972 and lasted essentially ten years,[3] seventeen advisory panels of qualified experts evaluated the safety, effectiveness, and labeling accuracy of each category of OTC drugs. 21 U.S.C. § 330.10(a); Ganley Decl. ¶¶ 9, 11 & n. 2. Each panel

[3] The original seventeen panels completed their work by 1981, but FDA has since identified several additional categories of OTC drug products recently reviewed by newly formed expert panels. Ganley Decl. ¶ 11 n. 2; *see, e.g.,* 68 Fed. Reg. 32232 (May 23, 2003) (panel report for antiplaque drug products).

reviewed at least one category of OTC drugs; however, some drug categories—such as topical antimicrobial drug products—required review by multiple panels. Ganley Decl. ¶ 11. The panels were comprised of voting members from the scientific community including physicians, pharmacologists, and toxicologists, and nonvoting members representing the interests of consumers and industry. *Id.* ¶ 9. FDA invited the public to submit data and information to the panels pertaining to, among other things, labeling, active ingredients, animal safety data, human safety data, and efficacy data. *Id.*; 21 C.F.R. § 330.10(a)(2). The panels were permitted to meet "as often and for as long as is appropriate" to review the submissions. Ganley Decl. ¶ 9; 21 C.F.R. § 330.10(a)(3). In some instances, the panels held hearings during which the public was afforded an opportunity to present its views. *Id.* In total, the panels reviewed and evaluated more than 14,000 volumes of submitted data and other information, collectively met over 500 times on more than 1,000 days, and deliberated, on average, 4.5 years each. Ganley Decl. ¶ 11.

After reviewing all scientific evidence submitted to it, each advisory panel was required to prepare and submit a report to FDA. 21 C.F.R. § 330.10(a)(5); Ganley Decl. ¶ 9. Each report classified the active ingredients for the subject class of drugs in one or more of the following three categories:

- Category I: Conditions under which the drugs would be generally recognized as safe and effective and not misbranded;
- Category II: Conditions under which the drugs would *not* be generally recognized as safe and effective or would be misbranded; or
- Category III: Conditions for which the available data were insufficient to classify as Category I or II and for which more testing was required.

21 C.F.R. § 330.10(a)(5)(i-iii); Ganley Decl. ¶ 10. An active ingredient could have multiple classifications; for example, it might be Category I for one intended use and Category II for another intended use (*i.e.*, drugs containing that active ingredient might be generally recognized

as safe and effective for some intended uses, but not safe and effective for others). Ganley Decl. ¶ 10. By 1981, the panels had examined all relevant data, heard witnesses, developed recommendations, and submitted to FDA reports covering each of the 26 classes of OTC drugs. *Id.* ¶ 11.

2. Phase II: Advance Notice of Proposed Rulemaking

During the second phase of the OTC Drug Review, the Commissioner published in the *Federal Register* an advance notice of proposed rulemaking for each drug category that contained the full panel report or summarized the panel's conclusions and recommendations. 21 C.F.R. § 330.10(a)(6); Ganley Decl. ¶ 12. FDA was free to accept, reject, or further consider a panel's conclusions and recommendations. *See* 37 Fed. Reg. at 9470; Ganley Decl. ¶ 12. In addition, FDA often presented some of its own views in the ANPRMs, and, as needed, requested the public to submit additional information. Ganley Decl. ¶ 12. As required by its regulations, FDA obtained full public comment on each ANPRM. *Id.*; 21 C.F.R. § 330.10(a)(6)(iv). The second phase is now essentially complete; by 1982, FDA had published ANPRMs for each original class of OTC drugs. [4] Ganley Decl. ¶ 12.

3. Phase III: Tentative Final Monograph

During the OTC Drug Review's third phase, which is still ongoing, the Commissioner develops and publishes a proposed rule containing a TFM that establishes those conditions under which a class of OTC drugs is generally recognized as safe and effective and not misbranded. 21 C.F.R. § 330.10(a)(7); Ganley Decl. ¶ 13. In the preamble to each proposed rule containing a TFM, FDA first presents its views on relevant scientific, medical, policy, and legal issues affecting the category of OTC drugs. Ganley Decl. ¶ 14. Each TFM classifies the active

[4] *See* note 3, supra.

ingredients for the relevant drug category into Category I, II, and III, as described above. *Id.* ¶ 13. If there is any significant question as to an active ingredient's safety, the active ingredient is placed in Category II, not Category III. *Id.* By 1994, FDA had issued TFMs for each original category of OTC drugs. *Id.* ¶ 14.

Issuance of a TFM facilitates substantial public participation in the OTC Drug Review by interested persons, such as the product manufacturers, consumers, and advocacy groups, such as NRDC. *Id.* ¶ 15; *see also* 37 Fed. Reg. at 9471. Such persons are given a minimum of 90 days (often 180 days for larger, more complex monographs) to submit written comments or objections to the TFM and to request an oral hearing before the Commissioner. 21 C.F.R. § 330.10(a)(7)(i); Ganley Decl. ¶ 15. Within 12 months after publication, an interested person may submit new data and information to FDA to support a condition excluded from the TFM. 21 C.F.R. § 330.10(a)(7)(iii); Ganley Decl. ¶ 15. After the final day for submission of new data and information, the rebuttal comment period begins; interested persons may submit new data and information within 14 months after publication of a TFM. 21 C.F.R. § 330.10(a)(7)(iv); Ganley Decl. ¶ 15. Given the lengthy comment and rebuttal periods, FDA often receives extensive, voluminous comments and new data and information after publishing a TFM. Ganley Decl. ¶ 15. In addition, the agency frequently receives new data and information after the comment and rebuttal periods close, which the Commissioner may consider for good cause. *Id.*; 21 C.F.R. § 330.10(a)(7)(v).

Because of the importance of the public's participation in the OTC Drug Review, FDA expends significant resources reviewing comments, data, and information after a TFM publishes. Ganley Decl. ¶ 16. The comments frequently relate to complex scientific, medical, policy, and legal issues. *Id.* FDA assigns employees with the relevant training to analyze the comments. *Id.*

Moreover, comments sometimes raise issues that require FDA to propose a revised TFM and permit time for a new round of notice and comment. *Id.* ¶ 19. In addition, TFMs must undergo a thorough interagency review process before they are published, including review by the Department of Health and Human Services, and, in some cases, by the Office of Management and Budget. *Id.* ¶¶ 18-19 & n. 4. These agencies may raise issues that require referral back to FDA for resolution. *Id.* ¶ 19.

4. Phase IV: Final Monograph

During the fourth phase of the OTC Drug Review, the Commissioner publishes a final monograph establishing conditions under which a category of OTC drugs is generally recognized as safe and effective and not misbranded. 21 C.F.R. § 330.10(a)(9). When promulgated, only Category I conditions become part of a final monograph; all Category II and III conditions become "nonmonograph conditions." Ganley Decl. ¶ 16. In simple terms, a drug may be marketed under circumstances that qualify it for Category I treatment under the relevant monograph. A drug may not be marketed under circumstances that qualify it for Category II or III treatment under the relevant final monograph, and would be considered a new drug subject to premarket approval. *See* 21 U.S.C. § 355.

Before issuing a final monograph, however, FDA must review and evaluate all data and information submitted after publication of the TFM, as described above, together with the entire record. Ganley Decl. ¶ 16. Prior to promulgation of a final monograph, the agency's tentative conclusions, including the classification of active ingredients, are subject to reconsideration based on new information that may be submitted to FDA. *Id.* ¶¶ 16-19; *see Hayes*, 818 F.2d at 894. FDA regulations governing the OTC Drug Review provide that any testing necessary to resolve safety or effectiveness issues resulting in a Category III classification, and submission to

FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process—before the establishment of a final monograph. 21 C.F.R. § 330.10; *see also* 59 Fed. Reg. 31402, 31403 (June 17, 1994); 46 Fed. Reg. 47740 (Sept. 29, 1981); Ganley Decl. ¶ 33. Like TFMs, draft final monographs must undergo a thorough review process within FDA, the United States Department of Health and Human Services and, for certain monographs, the Office of Management and Budget. Ganley Decl. ¶¶ 16-19.

C. FDA's Consistent Progress on the OTC Drug Review

FDA has made significant strides in advancing the OTC Drug Review. Its first priority was to complete the panel reviews for all drug categories and publish their reports. *Id.* ¶ 30. FDA then focused its attention on issuing TFMs for each category, followed by final monographs. *Id.* FDA has issued final monographs for the majority of OTC drug categories, which are published in the Code of Federal Regulations at 21 C.F.R. Parts 331-358. *Id.* ¶ 37. As of December 1, 2010, FDA has published over 150 proposed rules (including TFMs, amended TFMs, and proposed rules to amend final monographs) and 130 final rules (including final monographs and amended final monographs). *Id.* FDA's website provides a detailed status of OTC drug rulemakings. *See* Milestone Status Documents, available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/default.htm (last accessed 12/10/10).

This progress has not come without challenges. In the absence of accurate estimates of the size of the endeavor, and with a sincere desire to complete the project as expeditiously as possible, in retrospect, FDA was overly optimistic about how long the review would take. Ganley Decl. ¶ 29. For instance, in 1972, FDA thought that most drugs were compounded from 200 active ingredients, when, in fact, the OTC Drug Review eventually encompassed some 800

active ingredients (plus combinations of those ingredients), many in different drug products with varying intended uses.[5] *Id; see* 37 Fed. Reg. at 86; 37 Fed. Reg. 9464 ("The [FDA] believes that the therapeutic category approach to OTC drugs is appropriate, since there are only an estimated 200 active ingredients in the thousands of OTC drugs now marketed . . . ."). FDA was also unaware of the paucity of quality scientific evidence in medical literature available for review by the panels in reaching final conclusions on the general recognition of safety and effectiveness. *Id.* And at various times, changes in regulatory priorities, unanticipated events, court decisions, and crises have unavoidably required staff attention and resources, and affected the issuance of monographs. *See id.* ¶¶ 31-36.

Furthermore, the OTC Drug Review is never officially complete for any particular product class. *Id.* ¶ 21. After promulgation, a final monograph may be amended, either on the Commissioner's own initiative or upon the petition of an interested person. 21 C.F.R. § 330.10(a)(12). OTC drug monographs are continually updated to add ingredients, labeling, or other pertinent information, as needed. Ganley Decl. ¶ 21. FDA now is considering several categories of marketed OTC drug products as part of the OTC Drug Review that were not reviewed by the original panels. *See, e.g.*, 68 Fed. Reg. 32232 (May 29, 2003) (panel report for antiplaque drug products); 54 Fed. Reg. 50240 (Dec. 5, 1989) (call-for-data notice on certain eyewash drug products); *Id.* ¶ 11 n. 2.

D. FDA's Enforcement Discretion and Authority to Remove Active Ingredients from Consideration to Protect Public Health

Drugs that do not have an approved NDA and do not otherwise comply with an applicable final monograph are unapproved new drugs. FDA, however, generally exercises its

[5] Each active ingredient differs based on a variety of characteristics (e.g., chemical, structure, mode of action, spectrum of antimicrobial activity, absorption through the skin, time to effect, duration of effect, etc.).

enforcement discretion to permit OTC drug products that do not have an approved NDA to be marketed during the pendency of the OTC Drug Review, provided that four conditions are met: (1) the drug product or similarly formulated and labeled products were marketed as OTC drugs at the inception of the OTC Drug Review; (2) the drug product does not constitute a hazard to health; (3) the drug product is not a prescription drug within the meaning of 21 U.S.C. § 323(b); and (4) the drug product is an OTC drug and does not bear claims for serious disease conditions that require the attention and supervision of a licensed practitioner. 68 Fed. Reg. 75585, 75590-91 (Dec. 31, 2003); Ganley Decl. ¶ 28.

Accordingly, FDA pursues regulatory action against drugs subject to the OTC Drug Review that pose a hazard to consumers or that otherwise violate the Act. Ganley Decl. ¶ 28; FDA Compliance Policy Guide ("CPG") Sec. 450.200, Drugs – General Provisions and Administrative Procedures for Recognition as Safe and Effective, available at http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074388.htm; Compliance Policy Guide Sec. 440.100 Marketed New Drugs Without Approved NDAs and ANDAs, http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidance Manual/ucm074382.htm.

Additionally, before a final monograph is published, FDA identifies and removes (via *Federal Register* notice) active ingredients that pose a threat to public health from the marketplace and from consideration under the OTC Drug Review. Ganley Decl. ¶¶ 26-27. FDA has done so on a number of occasions. *Id.* ¶ 27. Some notable examples include hexachlorophene, an active ingredient used in topical antimicrobial skin cleanser products, 37 Fed. Reg. 219 (Jan. 7, 1972), 37 Fed. Reg. 20160 (Sept. 27, 1972), codified at 21 C.F.R. § 250.250; TBS, an antibacterial ingredient, 39 Fed. Reg. 33102 (Sept. 13, 1974), 40 Fed. Reg.

50527 (Oct. 30, 1975), codified at 21 C.F.R. § 310.508; zirconium, an antiperspirant ingredient, 40 Fed. Reg. 24328 (June 5, 1975), 42 Fed. Reg. 41374 (Aug. 16, 1977), codified at 21 C.F.R. § 310.510; chloroform, 41 Fed. Reg. 15026 (Apr. 19, 1976), 41 Fed. Reg. 26842 (June 29, 1976), codified at 21 C.F.R. § 310.513; and sweet spirits of nitre, used to reduce fevers in infants, among other uses, 45 Fed. Reg. 43400 (June 27, 1980), codified at 21 C.F.R. § 310.502. FDA went further for the category of active ingredients intended for use as OTC daytime sedatives, concluding that no ingredients labeled for such use are GRAS/E. 44 Fed. Reg. 36378 (June 22, 1979). The agency also has banned active ingredients for which the agency lacks adequate data to establish general recognition of the safety and effectiveness for specified uses and for which no new data are available. *See, e.g.*, 55 Fed. Reg. 46914 (Nov. 7, 1990); 58 Fed. Reg. 27636 (May 10, 1993); 67 Fed. Reg. 31123 & 31125 (May 9, 2002); codified at 21 C.F.R. § 310.545.

II. Monograph for Topical Antimicrobial Drug Products

The monograph for topical antimicrobial drug products is one of the largest, most complex, and controversial of the OTC monographs. Ganley Decl. ¶ 38. That monograph consists of six subparts (soon to be eight subparts, as discussed below), each of which must proceed in accordance with the OTC Drug Review's four phases. *Id.* ¶¶ 42, 44. The monograph encompasses the entire class of OTC topical antimicrobial drug products, which are used to kill or inhibit the growth of microorganisms such as bacteria. *Id.* ¶ 38. Antimicrobials include antiseptics and both natural and synthetic antibiotics. *Id.*

Because of its size and complexity, FDA convened several panels to consider drug products covered by the monograph for topical antimicrobial drug products. *Id.* ¶ 11. After requesting data and information from the public, 37 Fed. Reg. 235 (Jan. 7, 1972), 37 Fed. Reg. 6775 (Apr. 4, 1972), the first antimicrobial advisory review panel convened for a total of 35 days

over a one and a half year period. Ganley Decl. ¶ 40. FDA published that panel's report in an ANPRM in September 1974. *Id.*; 39 Fed. Reg. 33103 (Sept. 13, 1974). After numerous requests, FDA granted two extensions to the ANPRM's public comment period, in part because of the complexity of the panel's report. Ganley Decl. ¶ 40; *see* 39 Fed. Reg. 35675 (Oct. 3, 1974); 39 Fed. Reg. 37066 (Oct. 17, 1974). After addressing and analyzing issues contained in over 100 public submissions, FDA issued the first TFM for topical antimicrobial drug products ("1978 TFM"). 43 Fed. Reg. 1210 (Jan. 6, 1978); Ganley Decl. ¶ 40. In February 1980, a second advisory review panel submitted its panel report to FDA after meeting to review additional antimicrobial drug products. Ganley Decl. ¶ 40; *see, e.g.*, 47 Fed. Reg. 12480 (Mar. 23, 1982) (ANPRM based on recommendations of second antimicrobial advisory review panel). The second antimicrobial panel was one of the longest-running panels, conducting 54 meetings lasting a total of 128 days over 6.5 years. Ganley Decl. ¶ 40. Additionally, during the early 1980s, FDA received recommendations relating to topical antimicrobial products from different panels and reopened the administrative record in order to review these recommendations. *Id.*; s*ee, e.g.*, 47 Fed. Reg. 436 (Jan. 5, 1982); 47 Fed. Reg. 22324 (May 21, 1982); 47 Fed. Reg. 39406 (Sept. 7, 1982).

Since the 1978 TFM issued, the scope and structure of the monograph for topical antimicrobial drug products has evolved in considerable and significant respects. Ganley Decl. ¶ 41. For instance, as originally conceived and tentatively proposed in the 1978 TFM, FDA planned to publish one final monograph covering all topical antiseptic drug products, which are used to kill or inhibit the growth of microorganisms on the skin. *Id.* However, in the early 1980s, FDA merged other, related therapeutic categories with the topical antimicrobial drug monograph. *Id.*; *see also*, *e.g.*, 47 Fed. Reg. 436 (Jan. 5, 1982) (adding 18 more active

ingredients to the antimicrobial rulemaking); 47 Fed. Reg. 12480 (Mar. 23, 1982) (ANPRM for antifungal drug products); 47 Fed. Reg. 22324 (May 21, 1982) (adding four more active ingredients to the antimicrobial rulemaking). Although administratively efficient, this created additional subcategories by therapeutic use and more active ingredients to consider under the topical antimicrobial monograph. *Id.* FDA thereafter finalized portions of the monograph. *See* 52 Fed. Reg. 47312 (Dec. 11, 1987) (final monograph for antibiotic drug products); 56 Fed. Reg. 41008 (Aug. 16, 1991) (acne drug products); 58 Fed. Reg. 49890 (Sept. 23, 1993) (antifungal drug products). Because of its size and complexity, FDA divided other portions of the original monograph into subparts so that FDA could separately assess safety, effectiveness, and proper labeling for the range of different uses of antimicrobial drug products. Ganley Decl. ¶ 41; *see also* 59 Fed. Reg. 31402, 31403 (June 17, 1994). FDA determined that it was appropriate to reissue TFMs and final monographs for these new subcategories of antimicrobial drug products. *Id.* For example, in 1991, FDA issued a TFM for First Aid Antiseptic Drug Products, 56 Fed. Reg. 33644 (July 22, 1991), followed by a TFM for Health-Care Antiseptic Drug Products in 1994, 59 Fed. Reg. 31402 (June 17, 1994).

Accordingly, the monograph for topical antimicrobial drug products is currently comprised of six product categories—each of which requires a separate submonograph:

- First Aid Antiseptic Drug Products;
- First Aid Antibiotic Drug Products;
- Antifungal Drug Products;
- Acne Drug Products;
- Health-Care Antiseptic Drug Products; and
- Diaper Rash Drug Products.

Ganley Decl. ¶ 42.

Because each subcategory functions as its own monograph (and constitutes a separate rulemaking), FDA must publish separate TFMs and final monographs for each. *Id.* ¶ 41. FDA has promulgated final monographs for half of the drug product categories within the monograph for topical antimicrobial drug products: First Aid Antibiotic Drug Products, Topical Antifungal Drug Products, and Topical Acne Drug Products. 21 C.F.R. Part 333, Subparts B through D; Ganley Decl. ¶ 42. Of the remaining drug product categories within the topical antimicrobial monograph, FDA next expects to finalize Health-Care Antiseptic Drug Products. Ganley Decl. ¶ 43.

A. Next Step Toward Completion of the Topical Antimicrobial Monograph: Health-Care Antiseptic Drug Products

Finalizing the portion of the topical antimicrobial monograph for Health-Care Antiseptic Drug Products is currently one of the highest priorities of the OTC Drug Review. Ganley Decl. ¶ 43. The TFM currently in place for these products is the 1994 TFM for Health-Care Antiseptic Drug Products ("1994 TFM"), which encompasses antiseptic drug products marketed for use by health care professionals (*e.g.*, health care personnel handwashes, patient preoperative skin preparations, surgical hand scrubs) and for personal use by consumers (*e.g.*, handwashes for personal use in the home). *Id.*; 59 Fed. Reg. 31402. After publishing the 1994 TFM, FDA diligently worked to finalize the monograph for Health-Care Antiseptic Drug Products but faced several obstacles in the years that immediately followed. Ganley Decl. ¶¶ 70-79.

The 1994 TFM comment period closed in February 1996, over a year and a half after FDA issued the TFM. *Id.* ¶ 71. FDA received 50 submissions, many voluminous, even before the comment period closed. *Id.* In total, the public submitted over 40 volumes of comments, data, and other information to FDA in response to the 1994 TFM, totaling well over 10,000 pages. *Id.* Because parties with highly polarized interests submitted comments that assumed

conflicting and antagonistic positions, the comments raised issues that required careful, detailed explanations and eluded simple and speedy resolution. *Id.* ¶ 72. FDA reviewed all comments, rebuttal comments, and data and information submitted in response to the 1994 TFM as well as newly available data. *Id.* As needed, physicians, scientists, statisticians, and regulators throughout FDA and attorneys in the agency's Office of Chief Counsel worked to resolve medical, scientific, policy, and legal issues pertaining to ingredient classification, drug effectiveness testing and formulation, and drug labeling, among others, before the agency could issue a final monograph. *Id.* As is typically the case with such lengthy, complex, and contentious OTC Drug Review rulemakings, it took FDA several years to resolve the many issues raised in the submissions. *Id.*

The comment review process and the evolving nature of the science underlying the 1994 TFM has presented FDA with unique challenges. *Id.* ¶ 74. On four separate occasions, FDA has sought advice from the Nonprescription Drugs Advisory Committee ("NDAC"), an advisory review committee comprised of experts outside of FDA. *Id.* NDAC has replaced the advisory review panels that disbanded after FDA completed the first phase of the OTC Drug Review and considers issues of importance as they arise. Ganley Decl. ¶ 22; *see also* 21 C.F.R. § 14.100(c)(17). In response to public comments on the 1994 TFM, FDA referred to NDAC difficult and controversial issues relating to antimicrobial and antibiotic resistance, performance expectations and testing requirements, and appropriate effectiveness criteria (*i.e.*, the minimum standards that a drug product must meet to be considered generally recognized as effective when testing in clinical simulation studies). *Id.* ¶¶ 58, 74-76 & n. 14. The following briefly details the issues that FDA referred to NDAC since the 1994 TFM and FDA's related reopening of the record for the monograph:

- **January 1997:** NDAC (along with the Anti-Infective Drugs Advisory Committee) met to consider the role that antimicrobial drug products may play in the development of antimicrobial and antibiotic resistance. Specifically, FDA sought advice on the clinical significance and implications of some laboratory data that demonstrated antimicrobial and antibiotic resistance. NDAC concluded that FDA did not have sufficient data to take action but recommended that FDA work with industry to establish surveillance mechanisms to address antimicrobial and antibiotic resistance. *Id.* ¶ 58.

- **July 1998:** NDAC met to discuss performance expectations and testing requirements for topical antiseptic drug products used by healthcare professionals in response to comments to the 1994 TFM on these issues. NDAC recognized concerns raised by manufacturers that FDA needed to revise the final formulation testing it proposed in the 1994 TFM. *Id.* ¶ 75.

- **May 2003:** On May 29, 2003, after receiving another 54 submissions and 16 Citizen Petitions, FDA reopened the record for the monograph. 68 Fed. Reg. 32003 (May 29, 2003). FDA found good cause for the agency to consider new data and information relevant to the final classification of active ingredients and the testing criteria outlined in the 1994 TFM. The rulemaking remained open until August 27, 2003, during which time FDA received an additional 56 submissions and another Citizen Petition. The comments pertained to the agency's tentative conclusions on safety and effectiveness for many of the active ingredients considered as well as many other aspects of the monograph including the proposed effectiveness criteria, testing requirements, and labeling. Ganley Decl. ¶ 73.

- **March 2005:** NDAC met to consider the 1994 TFM's testing requirements and effectiveness criteria for topical antiseptic drug products used by healthcare professionals. NDAC recommended that FDA make numerous changes to the 1994 TFM's testing design requirements, which FDA has since addressed internally. After considering study design and surrogate endpoints used to demonstrate the effectiveness of healthcare antiseptics, NDAC unanimously agreed that there was not compelling evidence to change the effectiveness standard as set forth in the 1994 TFM. *Id.* ¶ 76.

- **October 2005:** NDAC met to review FDA's analysis of available data on the risks and benefits of consumer handwashes. In considering the effectiveness standard for these products, NDAC concluded that there was not adequate evidence to show that consumer handwashes provide an extra benefit over plain soap and water for reducing transmission of or preventing infection. Accordingly, NDAC recommended that FDA use a different effectiveness standard, one that requires that consumer handwashes provide a clinical benefit by demonstrating a reduction in infections, rather than using a bacterial log reduction standard (the difference in the number of bacteria recovered from the skin before and after treatment, expressed as a logarithm) as proposed in the 1994 TFM. At this time, NDAC also expressed concern about the societal consequences of the pervasive use of consumer antimicrobial products (not limited to drug products). *Id.* ¶¶ 77, 58.

Since FDA issued the 1994 TFM, and particularly following the October 2005 NDAC meeting on consumer antiseptics, FDA determined that antiseptics intended for use by health-care professionals differ in important ways from antiseptics for personal consumer use. *Id.* ¶¶ 43-44. For instance, in a hospital setting where health-care professionals may use antiseptics, the risk of exposure to pathogenic bacteria is high within a population that includes many individuals with weakened immune systems and an increased risk for serious infections. *Id.* ¶ 43. In the consumer setting, by contrast, the target population is comprised of generally healthy individuals and the risk of infection is relatively low. *Id.* Because the risks and benefits are typically very different between these populations, FDA has announced plans to reissue the 1994 TFM in multiple parts, addressing topical antiseptic drugs products intended for use by health care workers and consumers separately, and adding a new subcategory for topical antiseptic drug products marketed for use by food handlers. *Semiannual Regulatory Agenda*, 75 Fed. Reg. 21781, 21793 (Apr. 26, 2010); *Id.* ¶ 44. Thus, reflecting this change, the restructured monographs for topical antimicrobial drug products might be addressed separately for different product categories, for example:

- First Aid Antiseptic Drug Products;
- First Aid Antibiotic Drug Products [Final monograph issued];
- Antifungal Drug Products [Final monograph issued];
- Acne Drug Products [Final monograph issued];
- **Non-First Aid Antiseptic Drug Products, including**
    - Consumer Antiseptic Drug Products;
    - Health-Care Antiseptic Drug Products; and
    - Food Handler Antiseptic Drug Products; and
- Diaper Rash Drug Products.

Ganley Decl. ¶ 44. By restructuring the monographs, FDA will be able to separately assess and analyze the unique risk-benefit profile for each antiseptic use. *Id.* However, separate analytical

review will require the agency to issue new proposed and final rules for Consumer Antiseptic, Health-Care Antiseptic, and Food Handler Antiseptic Drug Products. *Id.*

FDA has already announced its plans to issue a proposed rule for Consumer Antiseptic Drug Products, which include antimicrobial soaps, antiseptic handwashes, and antiseptic hand rubs (sometimes referred to as hand sanitizers) that are intended for daily use by the public. *Id.*; *see also Semiannual Regulatory Agenda*, 75 Fed. Reg. at 21793. FDA chose to draft the proposed rule for Consumer Antiseptic Drug Products before the other antiseptic subcategories because of recent concerns regarding potential safety issues relating to some of the monograph's active ingredients, such as triclosan and triclocarban. Ganley Decl. ¶ 46. The agency expects to issue a proposed rule for Consumer Antiseptic Drug Products, or take other regulatory action related to these drug products, as soon as practicable. *Id.* ¶ 45.

B. New Scientific Developments Affecting Antiseptic Drug Products, Including the Active Ingredients Triclosan and Triclocarban

Triclosan and triclocarban may be added to a variety of products and applications to reduce or prevent bacterial contamination. Ganley Decl. ¶ 47. Triclocarban, and more commonly triclosan, may be used as a preservative in cosmetics and as an antiseptic active ingredient in certain consumer products (*e.g.*, hand soaps and toothpastes) and healthcare professional products (*e.g.*, healthcare personnel handwashes and surgical handscrubs). *Id.* When consumers use drug products containing triclosan or triclocarban, they may be exposed to these substances, for example by absorbing small amounts through the skin (*e.g.*, handwash) or in the mouth (*e.g.*, toothpaste). *Id.* ¶ 50. Because these substances are used in a wide variety of consumer products, however, it is challenging to conduct meaningful studies that can accurately characterize exposure in all settings where it occurs. *Id.* 47.

Triclosan and triclocarban are only two of the twenty-six active ingredients that FDA considered under the 1994 TFM. Ganley Decl. ¶ 48; *see* 59 Fed. Reg. at 31435-31436. The 1994 TFM classified triclosan as a Category III active ingredient for safety and effectiveness (*i.e.*, insufficient information/more testing required to determine GRAS/E) and triclocarban as a Category I ingredient for safety (*i.e.*, GRAS) and Category III ingredient for effectiveness (*i.e.*, GRAE). *Id.*

FDA's consideration of triclosan and triclocarban is not limited to the OTC Drug Review. Ganley Decl. ¶ 49. FDA has evaluated the safety and effectiveness of certain drug products containing triclosan and triclocarban, and FDA has approved NDAs for drug products containing these ingredients. *Id.* For instance, in 1997, FDA approved an NDA for Colgate Total Toothpaste, a product containing triclosan.[6] *Id.*

Despite concerted efforts to finalize the 1994 TFM after it issued, *see id.* ¶¶ 72-79, new scientific developments have led the agency to reconsider its previous safety and effectiveness conclusions for triclosan and triclocarban, as well as other active ingredients, *id.* ¶ 52. New data and information available to FDA after 1994, but particularly since 2005, pertain to at least five separate complex scientific issues: (1) antimicrobial and antibiotic resistance; (2) endocrine disruption; (3) increased exposure to consumer antimicrobial products, new dosage forms, and changes in use patterns; (4) the appropriate effectiveness standard for consumer antiseptic drug products; and (5) increased environmental exposure to antiseptic products. *Id.* ¶¶ 52-69, 77. In

[6] Triclosan has a wide-variety of other uses not pertinent to the OTC Drug Review, *i.e.*, as a disinfectant in household products (*e.g.*, cleansers, plastics, and textiles) and to inhibit bacterial growth on medical devices (*e.g.*, sutures and stents) and in commercial and industrial applications (*e.g.*, conveyor belts, ice machines). Ganley Decl. ¶ 47 n. 9. Uses of triclosan and triclocarban other than as active ingredients in topical antiseptics are not a subject of this proceeding.

light of the new data and information available, FDA is reconsidering its 1994 tentative conclusions, including its previous understanding of triclosan and triclocarban, before issuing a final monograph for topical antiseptic drug products. *Id.* ¶ 81.

1. Antimicrobial and Antibiotic Resistance

The first issue FDA is studying pertains to the role that antimicrobial products, particularly consumer antiseptic products, may play in the development of antimicrobial and antibiotic resistance. *Id.* ¶¶ 58-60. As noted above, FDA twice sought advice from NDAC on the role that antimicrobial drug products may play in the development of antimicrobial or antibiotic resistance–first in 1997 and later in 2005. *Id.* ¶ 58. Since 2005, FDA has continued to evaluate the available data concerning the possibility that antiseptic use may contribute to the development of antimicrobial and antibiotic resistance.[7] *Id.* ¶ 59. FDA has reviewed all available literature correlating reduced susceptibility to antibacterial active ingredients and antibiotic resistance and exposure to either triclosan or triclocarban. *Id.* Presently, numerous studies that have evaluated cross-resistance between antiseptics and antibiotics suggest that bacteria can develop altered susceptibilities to both antiseptics and antibiotics in the laboratory setting. *Id.* FDA is considering the clinical relevance of these laboratory studies and believes that the potential for antiseptics to contribute to changes in antibiotic susceptibility warrants further evaluation. *Id.*

2. Endocrine Disruption

The second issue requiring review relates to the recent theory that certain antiseptic active ingredients may have the potential to disrupt the body's endocrine system. *Id.* ¶¶ 53-57.

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[7] FDA also monitors antimicrobial resistance as a co-chair to the Interagency Task Force on Antimicrobial Resistance, which was created in 1999 to develop a national plan to combat antimicrobial resistance. Ganley Decl. ¶ 60 & n. 11; see Public Health Action Plan to Combat Antimicrobial Resistance, http://www.cdc.gov/drugresistance/actionplan/aractionplan.pdf.

The scientific community published its first study on triclosan and endocrine disruption in July 2000, just as FDA was tackling other issues affecting the monograph, such as antimicrobial and antibiotic resistance. *Id.* ¶¶ 54, 58. The science on endocrine disruption and antiseptic ingredients is still in its very early stages. *Id.* ¶ 54. Particularly since 2005, newly available literature on the endocrine disrupting potential of antiseptic active ingredients like triclosan and triclocarban has come to FDA's attention. *Id.* Although public interest on the subject is high, the existing data suggesting that triclosan may act as an endocrine disruptor are still very preliminary. *Id.*; *see* 75 Fed. Reg. 76461, 76462 (Dec. 8, 2010) (EPA notice stating that studies conducted since 2008 "led EPA to determine that additional research on the potential health consequences of endocrine effects of triclosan is warranted"). And triclosan studies are ongoing. 75 Fed. Reg. at 76462-76463 ("[R]esearch [on triclosan] is underway and will help characterize the human relevance and potential risk of the results observed from initial laboratory studies."). Even fewer endocrine-related studies exist for triclocarban. Ganley Decl. ¶ 54.

3. Increased Exposure to Consumer Antimicrobial Products

FDA is studying a third issue pertaining to new information about increased exposure to consumer antimicrobial products in the time period since FDA issued the 1994 TFM. The 1994 TFM's safety and effectiveness considerations did not account for increased exposure to consumer antimicrobial products for which the long-term impact on human health is unknown. *Id.* ¶¶ 61, 63. Nor did FDA's tentative conclusions consider the development of new antiseptic drug products such as hand rubs in varying dosage forms (*e.g.*, gels, sprays, liquids, and foams) and used as an alternative to, or a replacement for, traditional soap and water. *Id.* ¶ 62. New dosage forms of topical antiseptic drug products have become prevalent on the market over the last decade. *Id.*

In light of increased exposure to consumer antimicrobial products within the last ten years, FDA is concerned about the potential long-term impact of these substances on human health. *Id.* ¶ 63. To aid in the collection of additional data on long-term dermal exposure, in May 2008 FDA nominated triclosan to NIH's National Toxicology Program ("NTP") through FDA's National Center for Toxicological Research ("NCTR"). *Id.* ¶ 64. NTP's ongoing studies on triclosan began in February 2010 and include a dermal carcinogenicity study along with a series of toxicokinetic studies designed to provide data on the effects of long-term triclosan exposure. *Id.*

4. Effectiveness of Consumer Antiseptic Drug Products

Another recent issue FDA is considering relates to the effectiveness of antiseptics intended for daily consumer use. NDAC concluded in October 2005 that there was not adequate evidence to show that consumer antiseptics provide an extra benefit over plain soap and water for reducing transmission of or preventing infection. Ganley Decl. ¶ 77. NDAC recommended that consumer antiseptics should provide a clinical benefit by demonstrating a reduction in infections, rather than using a bacterial log reduction standard (the difference in the number of bacteria recovered from the skin before and after treatment, expressed as a logarithm) as proposed in the 1994 TFM. *Id.* In November 2008, FDA met with the Soap & Detergent Association and the Personal Care Products Council Antimicrobial Coalition to discuss new data and information on the effectiveness of antibacterial hand washes. *Id.* ¶ 78. These organizations presented a new study design for effectiveness, which FDA has evaluated internally. *Id.*

5. Environmental Exposure to Antiseptic Ingredients

Lastly, FDA is investigating the effects of increased environmental exposure to topical antiseptic drug products, including those containing triclosan and triclocarban. *Id.* ¶¶ 66-69.

The first influential review of the effect of pharmaceuticals in personal care products on the environment was published in 1999. *Id.* ¶ 66. The scientific community is beginning to study the presence of these substances in the environment, potential accumulation in human and animal tissues (bioaccumulation), the possible breakdown of such substances into potentially harmful byproducts, and any resulting biological activity. *Id.*

FDA directed its attention to this issue in 2007 when it began collaborating with EPA to assess the impact that active ingredients in antiseptic drug products have on the environment. *Id.* Currently, FDA continues to collaborate with EPA to further study the environmental impact of all active ingredients subject to the topical antimicrobial monograph. *Id.* ¶ 69. To stay apprised of the rapidly developing scientific research in this area, earlier this year, FDA published a request for data and information regarding the potential environmental impact of certain OTC monograph ingredients, including triclosan. 75 Fed. Reg. 7606 (Feb. 22, 2010). FDA will consider whether any data and information received as well as the agency's ongoing environmental review should be considered as part of the monograph for topical antimicrobial drug products. Ganley Decl. ¶ 69.

For the issues discussed above as well as other topics considered by NDAC (such as final formulation testing), FDA has regularly conducted public meetings with interested members of the public, responded to Citizen Petitions, sent feedback letters addressing study protocols to industry, collaborated with other agencies when necessary, and responded to Congressional and press inquiries. *Id.* ¶ 79.

C. Current Scientific Data Support Continued Consideration of Triclosan and Triclocarban Under the OTC Drug Review

At this time, data submitted and otherwise available to FDA support the continued consideration of triclosan and triclocarban under the ongoing topical antimicrobial monograph

proceedings. Ganley Decl. ¶ 51; *see also Triclosan: What Consumers Should Know*, http://www.fda.gov/forconsumers/ consumerupdates/ucm205999.htm (last accessed, 11/15/10). New data and information related to these ingredients are continually emerging, and FDA is endeavoring to incorporate that data into the OTC Drug Review. Ganley Decl. ¶ 81. Other regulatory authorities like the Centers for Disease Control and Prevention ("CDC"), NIH, and EPA likewise have not concluded at this time that the products as currently used are harmful to humans. *See, e.g.*, Ganley Decl. ¶ 50 (CDC concludes that measurable amounts of triclosan found in the urine of its study participants "does not mean that the levels of triclosan cause an adverse health effect" but can help scientists plan and conduct needed studies on triclosan exposure and health effects); *id.* ¶ 57 (NIH informs Congress that it needs to "learn[] more" about endocrine disruption, "an important emerging public health concern"); *id.* ¶ 55 (EPA states: "[I]nsufficient scientific data are available . . . to allow for an evaluation of endocrine associated risks. The science related to measuring and demonstrating endocrine disruption is relatively new and validated testing methods are still being developed"); *id.* ¶ 64 (discussing FDA and NIH's interagency agreement to conduct ongoing studies of triclosan); CDC, Triclosan Fact Sheet, http://www.cdc.gov/exposurereport/ Triclosan_FactSheet.html ("The human health effects from exposure to low environmental levels of triclosan are unknown. . . . More research is needed to assess the human health effects of exposure to triclosan.") (last accessed, 11/15/10).

As such, FDA has chosen not to prohibit the use of OTC drug products containing triclosan or triclocarban. *Id.* ¶ 51. Rather, FDA has decided to reevaluate its 1994 TFM beginning with Consumer Antiseptic Drug Products, the category of uses most affected by these recent developments, issue proposed rulemaking as soon as practicable, request additional data and information, collaborate with EPA, NIH, and other federal agencies to further study these

ingredients to reach a sound scientific conclusion regarding the OTC use of these products. *Id.* ¶¶ 45, 51, 54, 56, 60 n.11, 64, 69, 80-81.

D. NRDC Recognizes the Active State of the Science Involving Triclosan

FDA is currently considering a Citizen Petition submitted in 2009 and supported by NRDC that acknowledges the new scientific developments affecting antiseptic drug products, the complexities of their varied uses, and the need for FDA to reissue the 1994 TFM. *See* Amended Citizen Petition to the United States Department of Health and Human Services, Food and Drug Administration, FDA 2005-P-0317, at 2, 37, available at http://www.regulations.gov/search/Regs/home.html#documentDetail?R =09000064809f1140. The Citizen Petition requests a ban on "widespread use of triclosan products and applications as registered by FDA" but not "on triclosan uses in controlled settings by medical and health professionals, such as in hospitals, medical care facilities and laboratories." *Id.* at 13-14. The document acknowledges "[c]ontinually-emerging scientific knowledge" and the recent "rapid march of modern scientific research and discovery" in the area of antimicrobial drug products, particularly triclosan. *Id.* at 3, 12. The Citizen Petition refers to "[r]ecent studies" on endocrine disruption and notes the growth of consumer antiseptics as a new phenomenon: "Just a few years ago, only a few dozen products containing antibacterial agents were being marketed for the home." *Id.* at 19, 22 (internal quotation marks omitted). Suggesting that FDA needs to revisit its 1994 TFM on antiseptic drug products, the Citizen Petition describes the agency's 1994 TFM in the face of new science as "both inadequate and outdated." *Id.* at 12-13.

SUMMARY OF THE ARGUMENT

NRDC cannot demonstrate any entitlement to relief. First, NRDC, an advocacy group, has failed to meet its burden of establishing standing to bring this challenge**.** Specifically, NRDC has failed to show a concrete and cognizable injury to its members. NRDC hypothesizes that its members may be subject to increased risks from exposure to triclosan and triclocarban, but, as NRDC must acknowledge, its members can and do take steps to avoid exposure to these ingredients.

Second, even if plaintiff had established standing, the undisputed material facts establish that FDA has not unreasonably delayed in completing the portion of the OTC Drug Review affecting topical antimicrobial drug products. In order to create the impression that FDA has been inactive for the last 30 years, NRDC focuses its attack on the monograph for topical antimicrobial drug products. But that ignores the steady progress that FDA has made in advancing the OTC Drug Review. Nothing in the Administrative Procedure Act ("APA") prohibits agencies from tackling extremely large regulatory programs over many years. NRDC also ignores the evolving science regarding triclosan and triclocarban. From a reading of NRDC's brief, one would think that the risks presented by triclosan and triclocarban are both certain and well-established. In truth, they are neither. Recent studies have raised new concerns about the safety and effectiveness of triclosan and triclocarban, and the science on this subject is still developing. FDA is moving as expeditiously as possible—within a long established regulatory framework—to address those concerns. Proceeding in this manner is not a violation of the APA.

ARGUMENT

I. Plaintiff Lacks Standing to Challenge the Status of FDA's Regulation of Antimicrobial Soaps Containing Triclosan or Triclocarban

Plaintiff bears the burden of establishing subject matter jurisdiction, including the elements of standing.[8] *Northeastern Fla. Chapter, Associated Gen. Contractors of Am. v. City of Jacksonville*, 508 U.S. 656, 663 (1993); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). At the summary judgment stage, plaintiff cannot rely on its pleadings alone to establish standing. Instead, "each [standing] element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation." *Lujan*, 504 U.S. at 561.

Where, as here, "the parties invoking federal jurisdiction are not 'the object of the government action or inaction' they challenge," "standing is 'substantially more difficult to establish.'" *Public Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 489 F.3d 1279, 1289 (D.C. Cir. 2007) (quoting *Lujan*, 504 U.S. at 562). NRDC's status as an advocacy group on environmental and public health issues does not in itself establish standing. "Disagreement with government action or policy . . . does not . . . constitute an 'injury'" for standing purposes. *Evans v. Hills*, 537 F.2d 571, 598 (2d Cir. 1976). *See also Gettman v. DEA*, 290 F.3d 430, 434 (D.C. Cir. 2002) ("'[A] mere 'interest in a problem,' no matter how longstanding the interest and no matter how qualified the organization is in evaluating the problem, is not sufficient by itself . .

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[8] NRDC's invocation of Rule 52 in support of its motion for summary judgment is misplaced. Rule 52 sets forth requirements for cases in which a trial on the facts is to be held. In APA litigation, however, "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). *See* 5 U.S.C. § 706 ("The reviewing court shall . . . compel agency action unlawfully withheld or unreasonably delayed . . . In making the foregoing determination[], the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error."). There is no need for a trial in this case, and therefore plaintiff's invocation of Rule 52 is not appropriate.

. .'") (quoting *Sierra Club v. Morton*, 405 U.S. 727, 739 (1972)); *Freedom from Religion Found., Inc. v. Chao*, 433 F.3d 989, 998 (7th Cir. 2006) ("A lawsuit based on . . . a mere disagreement with the government policy . . . is hardly the case and controversy within the jurisdiction of the federal courts."). Because an Article III court should not be called upon to decide "abstract questions of wide public significance," *Warth v. Seldin*, 422 U.S. 490, 500 (1975), NRDC must establish that it has suffered a concrete and particularized injury, meaning that the challenged conduct must have affected NRDC members in a personal and individual way. *Lujan*, 504 U.S. at 560 & n.1. Thus, NRDC's alleged concerns relating to exposure of the general population to triclosan and triclocarban and increased antibiotic resistance, *see* Compl. ¶¶ 61-62, do not establish a justiciable controversy for resolution by the courts.

NRDC alleges that is has standing through injuries to its members. Compl. ¶¶ 9-10; Memorandum of Law in Support of Plaintiff's Motion for Summary Judgment ("NRDC Br.") at 24-26. To have representational standing, an organizational plaintiff must demonstrate that its "members would otherwise have standing to sue in their own right, [that] the interests at stake are germane to the organization's purpose, and [that] neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *See Friends of the Earth, Inc. v. Laidlaw Envt'l Servs., Inc.*, 528 U.S. 167, 180-81 (2000). Accordingly, at least one member must be able to personally demonstrate all of the elements of Article III standing: (1) an injury-in-fact; (2) traceable to the challenged action of the defendant; and (3) redressable by a favorable decision. *Id.*; *see also Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S.

333, 343 (1977); *Warth*, 422 U.S. at 511. The declarations submitted by two NRDC members, Diana Owens and Megan R. Schwarzman, M.D., M.P.H., fail to satisfy NRDC's burden.[9]

Plaintiff grounds its representational standing, not on any known injuries suffered by its members, but instead on its members' "*concern[s]* about health *risks* from their exposure to triclosan and triclocarban in personal care products." *See* Compl. ¶ 9 (emphases added). However, a "hypothesized 'increased risk' has never been deemed sufficient 'injury'" to establish standing. *Ctr. for Law & Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1161 (D.C. Cir. 2005). Rather, to satisfy the requirement that the injury be "actual or imminent, not conjectural or hypothetical," *Lujan*, 504 U.S. at 560 & n. 1, plaintiff must demonstrate a "credible threat of harm" taking into account "the probability of harm" and "the severity of the probable harm." *Baur v. Veneman*, 352 F.3d 625, 637 (2d Cir. 2003);[10] *see, e.g., Korsinsky v. EPA*, 05 Civ. 859 (NRB), 2005 WL 2005 WL 2414744, at *2-3 (S.D.N.Y. Sept. 28, 2005) (plaintiff's increased risk allegations fail to meet standard articulated in *Baur v. Veneman*). *See also Public Citizen, Inc. v. National Highway Traffic Safety Admin.*, 513 F.3d 234, 237 (D.C. Cir. 2008) (standing based on increased risk of harm requires that "there was at least both (i) a *substantially* increased risk of harm and (ii) a *substantial* probability of harm with that increase taken into account") (emphasis in original).

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[9] NRDC has also submitted declarations by Sarah Janssen, M.D., Ph.D., M.P.H., Linda Lopez, and Vivian H.W. Wang, who are employed by NRDC and do not state that they are members of NRDC.

[10] The others cases cited by NRDC, NRDC Br. at 25, apply a special standard developed for environmental plaintiffs and therefore have little bearing on the matter before the Court. *See, e.g., Laidlaw Envt'l Servs., Inc.*, 528 U.S. at 183 ("We have held that environmental plaintiffs adequately allege injury in fact when they aver that they use the affected area and are persons 'for whom the aesthetic and recreational values of the area will be lessened' by the challenged activity.") (quoting *Sierra Club v. Morton*, 405 U.S. 727, 735 (1972)).

Plaintiff's evidence fails to meet the threshold of establishing a credible and probable, as opposed to hypothesized, increased risk of harm. The "concerns" alleged in this case do not establish injury-in-fact because of the steps that these individuals can and do take to avoid exposure to these substances. As plaintiff admits, individuals can—and the declarants do—choose to avoid purchasing and using antimicrobial soaps and other products containing triclosan and triclocarban. Schwarzman Decl. ¶ 7 ("I try to avoid products containing triclosan and triclocarban. I stopped purchasing products with these chemicals in 2006 when I first learned about their endocrine-disrupting potential."); Owens Decl. ¶ 7 ("Since learning about the health risks of triclosan, I have tried to purchase products that are triclosan-free.").

NRDC also admits that there are available, acceptable alternatives to triclosan- and triclocarban-containing products. For example, NRDC maintains that washing with regular soap and water is as effective as antimicrobial products. Compl. ¶ 39; NRDC Br. at 1, 5; Janssen Decl. ¶ 26. When sinks are not available, NRDC suggests that individuals can use alcohol-based hand-sanitizers that do not contain triclosan and triclocarban. *See* Triclosan and Triclocarban, available at http://www.simplesteps.org/chemicals/triclosan-and-triclocarban-antibacterials (last accessed on 12/09/10). In fact, NRDC's website urges its members to check labels, avoid purchasing and using triclosan- and triclocarban-containing products, and substitute alternate products and practices, as follows:

- Read the ingredients on your products, and get rid of anything containing Triclosan or Triclocarban. These chemicals are mostly in soap, but can also be in acne creams, cosmetics, and even some toothpastes! (http://switchboard.nrdc.org/blogs/gsolomon/antimicrobial_soaps_buyer_bewa.html (last accessed on 11/15/2010)).

- [G]ood hand washing techniques using regular soap and water is preferable to using so-called "antibacterial" soaps because regular soap and water are just as effective at eliminating "germs". So called "antibacterials", like triclosan or triclocarban are no more effective and carry potential health risks, so we advise avoiding their use. When you're

> on the go, alcohol-based hand sanitizers are also effective, but check the label for ingredients. All of the added "antibacterial" chemicals added to products must appear on the label as an active ingredient. (http://www.simplesteps.org/health/infants-children/antibacterials-qa (last accessed on 11/15/10).

NRDC's members' alleged concern regarding products that they can and do avoid does not constitute a concrete and particularized injury. In *Coalition for Mercury-Free Drugs. v. Sebelius*, 09 Civ. 0015 (RBW), --- F.Supp.2d ----, 2010 WL 2889182 (D.D.C. July 1, 2010), the court rejected a standing theory similar to the one urged by plaintiff here. That case involved a challenge to the FDA regulation of Thimerosol (which contains mercury) in vaccines. The court found that, because plaintiffs could have chosen to receive a vaccine that is Thimerosol-free, they had not suffered a concrete injury-in-fact:

> Given the market availability of mercury-free vaccination alternatives, and it being the plaintiffs' burden to demonstrate standing by asserting an injury in fact, *Sierra Club v. EPA*, 292 F.3d 896, 898 (D.C. Cir. 2002), which cannot be found with respect to the plaintiffs who assert standing based on their fear of the harmful effects of receiving mercury-based vaccines, the Court finds that the plaintiffs have not established standing based on this theory.

Id. at *7. Here, too, as NRDC admits, there are triclosan- and triclocarban-free alternatives available to individuals to alleviate their concerns and avoid the alleged injury.

Although both declarants admit that they purchase triclosan- and triclocarban-free products, they suggest that they are nevertheless injured because these products are not as "common" or "copious" as products containing the substances. Owens Decl. ¶¶ 7-8; Schwarzman Decl. ¶ 7. The declarants also assert that triclosan- and triclocarban-free products are more expensive than products without the substances. Owens Decl. ¶¶ 8, 17; Schwarzman Decl. ¶ 7. These allegations are insufficient. Neither declaration establishes that reasonable alternatives are unavailable. Owens Decl. ¶ 8. The Owens declaration merely states that a single "local" store has only one alternative. *Id.* Ms. Owens, who resides in Sarasota, Florida (*id.* ¶ 2), does not provide any information regarding availability of alternatives at any surrounding stores

(or, for that matter, mail order or online retailers). The Schwarzman declaration is even more deficient. It states that her ability to find triclosan- and triclocarban-free products "is not as hard as some areas," but that alternatives are more expensive. Schwarzman Decl. ¶ 7. The declaration provides no specific information regarding Ms. Schwarzman's attempts to find suitable alternatives, and provides no support for the assertion that triclosan- and triclocarban-free products are more expensive. Moreover, neither declarant explains why exposure to triclosan and triclocarban cannot be reduced or eliminated through use of alcohol-based hand sanitizers.[11]

Ms. Owens and Ms. Schwarzman also assert that they are or may be exposed to triclosan-containing products at work. Owens Decl. ¶¶ 13, 17-18; Schwarzman Decl. ¶ 9. Ms. Owens, a technician at a veterinary clinic, states that she washes her hands several times a day with soap and uses lotion supplied by the clinic, and that some or all of these products contain triclosan. Owens Decl. ¶¶ 12-13. She has discussed her concerns about triclosan exposure with the clinic owner, but does not feel comfortable asking the clinic owner to purchase triclosan-free products because she does not want to seem "pushy." *Id.* ¶ 18. She does not state whether she has

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[11] Moreover, whether or not the allegations in the Owens and Schwarzman declarations are true, FDA has no regulatory authority over the distribution and price of soaps and similar products: Third parties—the product manufacturers—control price and distribution. To confer standing, the injury has to be "fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court." *See Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976); *see, e.g.*, *Denney v. Deutsche Bank AG*, 443 F.3d 253, 266 (2d Cir. 2006) (finding standing where economic loss is a "direct result" of defendant's actions). Plaintiff must establish that it is "'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" *Lujan*, 504 U.S. at 561 (quoting *Simon*, 426 U.S. at 38). Plaintiff has not introduced any evidence demonstrating what, if any, effect FDA has had or might have on the price and availability of triclosan- and triclocarban-free soaps. Because plaintiff has not established that this alleged injury is traceable to the challenged action of FDA, or redressable by the relief sought by the complaint, plaintiff cannot rely on the alleged expense and relatively lower supply of alternative products to establish standing.

explored other alternatives, such as bringing her own soap and lotion to work. Dr. Schwarzman states that she works two shifts each month at a hospital where she has no control over the kind of soap that is provided. Schwarzman Decl. ¶ 9. She does not state that the hospital soap contains triclosan or triclocarban, or whether she has taken any steps to discover the contents or the hospital soap or to avoid using such soap, should it contain those substances.

These allegations do not establish concrete injuries that are causally related to FDA. The mere allegation that it requires some effort to use only triclosan- or triclocarban-free products in all aspects of their lives does not constitute injury-in-fact. In *Coalition for Mercury-Free Drugs v. Sebelius*, the court rejected plaintiffs' claims that the burden of delay and uncertainty in searching for mercury-free alternative vaccines established the injury or causation prongs required for standing. 2010 WL 2889182, at *7. Here, too, neither Ms. Owen's discomfort in exploring alternatives with her supervisor, nor Dr. Schwarzman's speculative statements regarding hospital soap, are sufficiently concrete and causally connected to FDA to establish standing.

II. FDA Has Not Unreasonably Delayed in Issuing the Monograph for Topical Antimicrobial Drugs

Courts review claims of "unreasonable agency delay" in agency rulemaking only under "extraordinary circumstances." *In re International Chemical Workers Union, et al.*, 958 F.2d 1144, 1149 (D.C. Cir. 1992).[12] Courts "must begin with recognition that an administrative agency is entitled to considerable deference in establishing a timetable for completing its proceedings." *Fox*, 93 F. Supp. 2d at 544, *vacated in part on other grounds sub nom. NRDC v. Muszynski*, 268 F.3d 91 (2d Cir. 2001) (citing *Hayes*, 818 F.2d at 896). FDA is entitled to

[12] Courts in this Circuit look to D.C. Circuit case law for guidance in considering claims of unreasonable delay. *NRDC v. Fox*, 93 F. Supp. 2d 531, 543 (S.D.N.Y. 2000).

"broad discretion to set its agenda and to first apply its limited resources to the regulatory tasks it deems most pressing." *Hayes*, 818 F.2d at 896. Moreover, the power of the Court to compel agency action does not include the power to engage in "pervasive oversight . . . over the manner and pace" in which agencies fulfill their statutory obligations. *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 66-67 (2004).

The federal courts have already considered—and upheld—the reasonableness of the OTC Drug Review's pace. In *Cutler v. Hayes*, 549 F. Supp. 1341, 1342 (D.D.C. 1982), the plaintiffs alleged, among other things, that FDA had unreasonably delayed in completing the OTC Drug Review. The district court ruled that FDA's actions did not amount to unreasonable delay. *Id.* 1348. Although the Court of Appeals vacated the judgment on the claim of unreasonable delay, it did not hold that the alleged 20-year delay was *per se* unreasonable, instead remanding the question of unreasonable delay to the district court. *Cutler v. Hayes*, 818 F.2d 879, 885, 887 (D.C. Cir. 1987). On remand, the district court again found no unreasonable delay and, after full briefing by the parties, granted the government's motion for summary judgment in September 1995, and dismissed the case with prejudice. *Cutler v. Hayes*, Civ. No. 81-2092 (TPJ) (D.D.C, Sept. 7, 1995); *see Barr Laboratories*, 930 F.2d 72, 76 (D.C. Cir. 1991) ("[W]e see no point in maintaining constant supervision over the FDA's progress.").

In any event, ignoring the fact that FDA spent more than a decade successfully litigating the pace of the OTC Drug Review, application of the relevant legal framework demonstrates that FDA is not engaged in unreasonable delay. In the leading case for evaluating the reasonableness of a particular administrative timetable, the D.C. Circuit identified the following six factors:

> (1) the time agencies take to make decisions must be governed by a 'rule of reason'; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might

> be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; (6) the court need not 'find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.'

Telecommunications Research and Action Center v. FCC ("*TRAC*"), 750 F.2d 70, 80 (D.C. Cir. 1984) (internal citations omitted); *see also Fox*, 93 F. Supp. 2d at 544. Application of these factors demonstrates that FDA is proceeding reasonably.

A. The Pace of FDA's Work on the Monograph for Topical Antimicrobial Drug Products, in Light of the Underlying Facts and Circumstances, Has Been and Continues to Be Reasonable

In evaluating whether the length of time expended in conducting an administrative proceeding constitutes unreasonable delay, courts typically apply the "rule of reason." *TRAC*, 750 F.2d at 80; *Public Citizen Health Research Group v. FDA*, 740 F.2d 21, 32 (D.C. Cir. 1984). "Resolution of a claim of unreasonable delay is ordinarily a complicated and nuanced task requiring consideration of the particular facts and circumstances before the court." *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 336 F.3d 1094, 1100 (D.C. Cir. 2003). "The 'rule of reason' requires the courts to evaluate alleged agency delay in light of the particular facts of a given case; accordingly, there is no hard-and-fast rule as to what amount of time constitutes an unreasonable delay." *Fox*, 93 F. Supp. 2d at 544 n. 8; *see also In re American Rivers & Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004) (no per se rule on the length of time that constitutes unreasonable delay); *Hayes*, 818 F.2d at 887 (alleged 20-year delay in completing the OTC Drug Review was not *per se* unreasonable). "[A]gency action should be compelled by the courts only when agency delay is 'egregious.'" *Fox*, 93 F. Supp. 2d at 544 (quoting *TRAC*, 750 F.2d at 79-80).

FDA has made steady progress in advancing the "monumental task" presented by the OTC Drug Review. *See McNeilab, Inc. v. Am. Home Prods. Corp.*, 501 F. Supp. 517, 533 (S.D.N.Y. 1980). Two noted scholars of federal food and drug law have described this task as "one of the most challenging rulemaking efforts undertaken by any government agency." R.A. Merrill & P.B. Hutt, Food & Drug Law 801 (3d ed. 2007). When FDA launched this project, it elected to comprehensively review classes of OTC drug products in multiple stages. Agencies have wide latitude to "attack a regulatory problem in phases" and "a phased attack often has substantial benefits" especially in highly technical regulatory areas. *Grand Canyon Air Tour Coalition v. FAA*, 154 F.3d 455, 471 (D.C. Cir. 1998). But the OTC Drug Review demonstrates that a phased approach can be immensely time- and resource-intensive. Ganley Decl. ¶ 25. As the D.C. Circuit has recognized, the OTC Drug Review's several stages have an "unavoidable long-term nature." *Hayes*, 818 F.2d at 901 n. 188.

The monograph for topical antimicrobial drug products (including its subparts)—among the largest, most complex, and controversial of the OTC monographs—has progressed through the OTC Drug Review's many stages. Ganley Decl. ¶ 38. It is not a unitary task involving a review of the safety and effectiveness of the active ingredients triclosan and triclocarban. Rather, the monograph and each of its subcategories encompass the entire class of OTC topical antimicrobial drug products and consider dozens of active ingredients that are labeled and marketed for different intended uses. *Id.* ¶¶ 38, 48. As such, the monograph's multi-faceted rulemakings affect a vast array of OTC drug products with a significant economic impact, and historically have generated a great deal of interest. *Id.* ¶¶ 38, 81 & n. 15.

Because of this degree of public interest and participation, FDA has granted extensions to the comment and rebuttal period at virtually every step of this rulemaking and found good cause

to reopen the administrative record numerous times to include new data and information submitted after the comment and rebuttal periods closed. *Id.* ¶ 39. Interest in this monograph remains high, as the rulemaking process continues to generate a considerable number of data submissions and other information. *Id.* In response to the 1994 TFM alone, the public submitted over 40 volumes of comments, data, and other information to FDA, totaling well over 10,000 pages. *Id.* ¶ 71.

The monograph for topical antimicrobial drug products has evolved differently than most other monographs. *Id.* ¶¶ 39-41. For instance, FDA originally proposed to issue a single monograph covering topical antiseptic drugs. *Id.* ¶ 41. After considering the evidence and issues raised by this category of drug products, however, FDA determined that it was necessary to divide the category into subparts so that FDA could separately assess safety, effectiveness, and proper labeling for the range of different uses of antimicrobial drug products. *Id.* In addition, FDA determined that other therapeutic categories should be merged with the monograph, creating additional subcategories by therapeutic use and more active ingredients for FDA to consider. *Id.*

Changing the scope of the applicable monographs meant that FDA needed to reissue tentative final and final monographs for new subcategories. *Id.* ¶¶ 41-42; *accord Weyerhaeuser Co. v. Costle*, 590 F.2d 1011, 1031 (D.C. Cir. 1978) (interpreting 5 U.S.C. § 553(b)(3) to require that an agency adopt a final rule that is a "logical outgrowth" of the proposed rule). Reissuing TFMs, while not routine for all rulemakings, is not unprecedented, especially when FDA is presented with new, complex issues that require resolution through public participation. *Id.* ¶ 19; *see, e.g.*, 51 Fed. Reg. 35136 (Oct. 1, 1986) (reissuing the laxative TFM to reflect new information on dosage strength and directions for use); 52 Fed. Reg. 31892 (Aug. 24, 1987)

(publishing a new antihistamine TFM to address new ingredients and changes to required warnings). FDA has already completed the process with respect to certain subcategories of antimicrobial drug products: FDA promulgated final monographs for First Aid Antibiotic Drug Products, Topical Antifungal Drug Products, and Topical Acne Drug Products. 21 C.F.R. Part 333, Subparts B through D; Ganley Decl. ¶ 42.

The other subparts can be finalized only after FDA, with the assistance of experts and broad public participation, has resolved all medical, scientific, policy, and legal issues raised during the regulatory process. Ganley Decl. ¶¶ 16-17, 24, 72. For antiseptic drug products, including handwashes and rubs, this includes complex issues relating to antimicrobial resistance, endocrine disruption, increased consumer and environmental exposure to antiseptic active ingredients, and appropriate effectiveness criteria and final formulation testing. *See id.* ¶¶ 52-69, 77. Other federal agencies have recognized FDA's continued efforts to finalize the monograph. 75 Fed. Reg. at 76463 ("[EPA] is . . . aware of FDA's ongoing effort to finalize the topical antimicrobial over-the-counter (OTC) drug monograph under which some products containing triclosan are regulated. EPA and FDA intend to collaborate and share information throughout . . . FDA's ongoing rule development.").

Currently, the agency is actively engaged in ongoing efforts to advance the progress of the monograph for topical antimicrobial drug products but needs time to collect, study, and address new and evolving data and information. *Id.* ¶¶ 80-81. Among other things, FDA is evaluating the clinical relevance of laboratory studies that suggest that bacteria can develop altered susceptibilities to antiseptics and antibiotics in laboratory settings; monitoring all new data on triclosan and triclocarban's potential to act as endocrine disruptors; resolving other issues considered by NDAC; evaluating the effects of increased human and environmental exposure to

antiseptic ingredients; and collaborating with EPA, NIH, and other federal agencies. *Id.* ¶¶ 54, 56, 60 & n.11, 64, 69, 80-81. Given the ongoing scientific concerns, the complexity of the scientific and policy issues involved, ongoing interagency collaboration, challenges to the monograph at nearly every step of its progress—all as the agency continued to work on other monographs and other priorities—FDA's activities regarding the monograph have been reasonable. *See id.* ¶¶ 31-36 (describing some changes in regulatory priorities, unanticipated events, court decisions, and crises that have unavoidably required staff attention and resources).

Furthermore, good agency decisionmaking, especially related to complex matters of evolving science, takes time, and FDA should be permitted to develop scientific bases for its regulations, especially ones of this complexity. *In re United Mine Workers of America Int'l Union*, 190 F.3d 545, 551-56 (D.C. Cir. 1999) ("[I]t is difficult for us to second-guess" the agency's time projections "in light of the host of complex scientific and technical issues involved" in the proposed rulemaking). As the D.C. Circuit has recognized, "FDA's procedures, designed to be thorough and well reasoned, do not permit quick decisions." *Community Nutrition Institute v. Young*, 773 F.2d 1356, 1361 (D.C. Cir. 1985).

NRDC's argument that FDA has acted unreasonably simply because it is taking "years," rather than "months," is wrong. NRDC Br. at 14. "The 'rule of reason' requires the courts to evaluate alleged agency delay in light of the particular facts of a given case; accordingly, there is no hard-and-fast rule as to what amount of time constitutes unreasonable delay." *Fox*, 93 F. Supp. 2d at 544 n. 8. NRDC's citation to cases involving different facts and different regulatory regimes is not particularly useful in determining whether FDA is acting reasonably here. "[NRDC's] reference to these cases demonstrates a lack of understanding of the governing law. .

. . None of these cases is helpful to the Court in resolving this claim." *Fox*. 93 F. Supp. 2d at 544 n. 8.

In any event, the cases cited by NRDC are inapposite. For example, *In re Bluewater Network*, 234 F.3d 1305 (D.C. Cir. 2000), involved the Coast Guard's six-year refusal to initiate rulemaking in the face of a congressional directive to begin rulemaking within one year. 234 F.3d at 1307. Here, to the contrary, FDA is actively engaged in rulemaking, and Congress has imposed no deadline for completion of the OTC Drug Review.

Likewise, each of the other cases cited by NRDC turns on its particular facts, and none of the cases involve a massive integrated regulatory effort similar to the OTC Drug Review. For instance, in *In re American Rivers and Idaho Rivers United*, 372 F.3d 413 (D.C. Cir. 2004), the petitioners sought a writ of mandamus to force the Federal Energy Regulatory Commission ("FERC") to act on a petition to protect salmon from hydropower operations in the Snake River basin. For six years, FERC declined to take any action on the petition, notwithstanding the fact that it had demonstrated an ability to act on similar petitions within a matter of months. 372 F.3d at 420 n. 14. In addition, FERC did not claim that other factors, such as "administrative convenience, practical difficulties in carrying out the legislative mandate, or need to prioritize in the face of limited resources," 372 F.3d at 420, contributed to the delay. *See also* NRDC Br. at 15 (citing *Public Citizen Health Research Group v. Brock*, 823 F.2d 626 (D.C. Cir. 1987) (agency's failure to promulgate regulation within time period previously set by court order was unreasonable, but did not warrant finding of contempt); *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150, 1154-58 (D.C. Cir. 1983) (failure to take discrete regulatory action in the face of "undisputed" health risks found to be unreasonable where mandamus would not disrupt other rulemakings); *Public Citizen Health Research Group v. FDA*, 724 F. Supp. 1013,

1020 (D.D.C. 1989) (FDA's decision to delay final rule and repropose regulation unreasonable where FDA admitted the reproposal was unnecessary)). None of these cases suggests that FDA is acting unreasonably by evaluating triclosan and triclocarban, among other active ingredients, in the context of a well-established regulatory scheme that is designed to preserve scientific integrity and permit thoughtful public participation.

Finally, NRDC claims that scientific "complexity" cannot justify FDA's failure to finalize the topical antimicrobial drug monograph. NRDC Br. at 22. But in assessing claims of unreasonable delay, courts routinely refuse to expedite agency action involving complex scientific and technical issues. *See Grand Canyon*, 154 F.3d at 476 (refusing to compel FAA action to address aircraft noise because of "the limits of [the Court's] institutional competence in the highly technical area at issue"); *Thomas*, 828 F.2d at 798 (refusing to expedite EPA regulations involving "complex scientific, technological, and policy questions"); *United Steelworkers of Am. v. Rubber Mfrs. Ass'n*, 783 F.2d 1117, 1120 (D.C. Cir. 1986) (denying petition for mandamus to compel OSHA rulemaking on expedited basis where complex scientific and technical issues involved made judicial imposition of "an overly hasty timetable" contrary to public interest); *Oil, Chemical & Atomic Workers Int'l Union v. Zegeer*, 768 F.2d 1480, 1487-88 (D.C. Cir. 1985) (refusing to order expedited agency rulemaking to protect underground miners from radon gas due to complex scientific and technical issues involved).

In addition, the monograph for topical antimicrobial drug products is not just scientifically complex; the multiple phases and significant public participation involved also makes it procedurally complex. Throughout the regulatory process, and particularly since issuing the 1994 TFM, FDA regularly has conducted public meetings, responded to Citizen Petitions, sent feedback letters addressing study protocols to industry, collaborated with other

agencies when necessary, and responded to Congressional and press inquiries. Ganley Decl. ¶ 79. Commenters have raised issues that FDA needed to address and, on several occasions, seek independent expert advice from NDAC. *Id.* ¶ 74. And there have been significant intervening events that must be addressed; for example, the recent concerns cited by NRDC about endocrine disruption and the increase of antibacterial products over the last few years. *See* Amended Citizen Petition to the United States Department of Health and Human Services, Food and Drug Administration, FDA 2005-P-0317, at 19,22, available at http://www.regulations.gov /search/Regs/home.html#documentDetail?R =09000064809f1140 (last accessed 12/09/10).

The relief NRDC seeks would unduly interfere with FDA's discretion to determine, as a matter of science and public health policy, the appropriate path forward, including further subdividing the monograph and issuing new TFMs.[13] FDA's decisions related to GRAS/E status, *i.e.*, whether a drug is or is not a new drug, and challenges to FDA's determination of what constitutes a new drug as defined by 21 U.S.C. § 321(p), are vested in the agency's discretion. And it is long- and well-established that FDA has primary jurisdiction to determine whether a drug is GRAS/E within the meaning of 21 U.S.C. § 321(p)(1). *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973). That decision "necessarily implicates complex chemical and pharmacological considerations," and "[t]hreshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court stays its hand." *Id.* at 654; *see also Farquhar v. FDA*, 616 F. Supp. 190, 193 (D.D.C. 1985)

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[13] Although just a year ago NRDC supported a Citizen Petition that characterized the 1994 TFM's tentative conclusions as "both inadequate and outdated" in light of new science, NRDC's requested relief would not permit FDA to reissue a TFM for, or take other regulatory action on, Consumer Antiseptic Drug Products. *See* Amended Citizen Petition to the United States Department of Health and Human Services, Food and Drug Administration, FDA 2005-P-0317, at 12-13, http://www.regulations .gov/search/Regs/home.html# documentDetail?R =09000064809f1140.

("New drug" status "is not a question for the judiciary to properly consider in the first instance. The FDA has the established procedures and expertise as well as the statutory authority to make this difficult determination."); *Premo Pharmaceutical Laboratories v. United States*, 629 F.2d 795 (2d Cir. 1980) (noting that FDA is "the publicly recognized repository of expertise" for determining which GRAS/E drug products are excluded from the Act's definition of a "new drug").

B. There Are No Fixed Statutory or Regulatory Deadlines

Next, "where Congress has provided a timetable or other indication of the speed with which it expects the agency to` proceed in the enabling statute," courts look to the relevant statutory scheme for further guidance in applying the rule of reason. *TRAC*, 750 F.2d at 80. Here, however, Congress did not set forth any procedures or a timetable for undertaking a review of OTC drugs. In fact, "the legislative history of the . . . Act contains no discussion of the OTC drug review since this program was wholly devised and implemented by FDA." *Hayes*, 818 F.2d at 898 n. 157. When FDA initiated this unprecedented task in 1972 by establishing regulations providing for monographs that specify those conditions under which classes of OTC drugs are generally recognized as safe and effective and not misbranded, it likewise did not provide a timetable for the issuance of monographs. 21 C.F.R. § 330.10.

NRDC's reference to FDA regulations that contain interim timetables for public comments reflects a profound misunderstanding of the regulatory process. NRDC Br. at 17. Completion of the entire monograph within the time period for a single round of comments is not feasible, and FDA's decision to reopen the proceedings to permit additional public participation is entitled to due deference. *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519, 546 (1978) ("Congress intended that the discretion of the

agencies and not that of the courts be exercised in determining when extra procedural devices should be employed." (emphasis in original)). FDA's regulations require a multi-phase review to establish scientific consensus on complex issues involving each class of OTC drugs. Panels were permitted to review public submissions "as often and for as long as is appropriate." 21 C.F.R. § 330.10(a)(3). Moreover, the OTC Drug Review provides for extensive public participation at each stage of the process—the opportunity to present oral views to the panel, *id.*, and request an oral hearing before the Commissioner, 21 C.F.R. § 330.10(a)(7)(i); participate in lengthy comment and rebuttal periods, lasting years even without often granted extensions, *see, e.g.*, 21 C.F.R. § 330.10(a)(7); and seek to reopen the administrative record to submit new data and information, 21 C.F.R. § 330.10(a)(7)(v). Thus, FDA regulations implementing the Act demonstrate that the agency envisioned that the OTC Drug Review would proceed at a pace that favors scientific integrity over haste.[14]

C. Consequences from Alleged Delay

"Third, and perhaps most critically, the court must examine the consequences of the agency's delay." *Hayes*, 818 F.2d at 898. In this case, the scientific evidence currently available underscores the lack of harm caused by agency delay, as FDA and other federal agencies agree that insufficient evidence exists to demonstrate that triclosan or triclocarban harm human health.

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[14] NRDC's contention that FDA has contravened the Act and the ruling of *Cutler v. Kennedy*, 475 F. Supp. 838 (D.D.C. 1979), by allowing indefinite marketing of Category III drugs pending issuance of a final monograph is wrong. NRDC Br. at 18. The Court in *Kennedy* invalidated FDA regulations that permitted the continued marketing of Category III OTC drugs subject to ongoing testing after the issuance of a final monograph. 475 F. Supp. at 855; *Hayes*, 818 F.2d at 885, 888. After *Kennedy*, FDA revised its regulations to require Category III testing to take place prior to finalizing monographs. *See* 46 Fed. Reg. 47741 (Sept. 29, 1981); *see also Hayes*, 818 F.2d at 885; Ganley Decl. ¶ 33. The same argument that NRDC makes here was dismissed in *Cutler v. Hayes*, 818 F.2d 879, 899 (D.C. Cir. 1987). The Court of Appeals in *Hayes* held that FDA's "revised regulations are consistent with the Act since they no longer authorize any marketing of drugs that officially have been labeled not generally recognized as safe and effective." 818 F.2d at 900.

Plaintiff's allegations of a detriment to human health are merely speculative. *See Fox*, 93 F. Supp. at 546; *see, e.g., Oil, Chemical & Atomic Workers Union*, 145 F.3d at 123 ("This presupposes . . . that the evidence before the agency sufficiently demonstrates that delay will in fact adversely affect human health to a degree which necessitates a priority response"); *Independence Mining Co. v. Babbitt*, 105 F.3d 502, 509-10 (9th Cir. 1997) (upholding district court finding that "potential impact . . . on public health and welfare was no more than speculative"). The public will benefit from FDA's thorough efforts to resolve numerous concerns expressed by individuals and consumer groups about all issues relating to the monograph, not just those pertaining to triclosan and triclocarban.

In addition, FDA may pursue regulatory action against OTC drugs containing triclosan and triclocarban that pose a hazard to consumers or that otherwise violate the Act. Ganley Decl. ¶ 28; *see also Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (agency's exercise of enforcement discretion is committed to agency's discretion by law and presumptively unreviewable); *Hayes*, 818 F.2d at 892.[15] FDA also retains the authority to specifically ban triclosan and triclocarban from the marketplace—as it has other active ingredients considered under the topical antimicrobial monograph—if there is a demonstrated health risk. Ganley Decl. ¶¶ 26-27; *see, e.g.*, 37 Fed. Reg. 219 (Jan. 7, 1972), 37 Fed. Reg. 20160 (Sept. 27, 1972) (hexachlorophene in topical antimicrobial skin cleansers). FDA can exercise this authority at any time, even before the monograph for topical antimicrobial drug products is complete. Ganley Decl. ¶ 26. To the extent that NRDC would otherwise suffer any harm, FDA's enforcement authority and ability to ban harmful drug ingredients significantly reduce it. For these reasons, the Court should give

[15] FDA may pursue an enforcement action against the manufacturer or drugs. *See, e.g.*, 21 U.S.C. §§ 332(a) (injunction), 334 (seizure).

FDA the "deference traditionally accorded an agency to develop its own schedule." *Hayes*, 818 F.2d at 898.

D. Other Priorities Vie for Limited FDA Resources

Another factor the Court should consider is "the effect of expediting delayed action on agency activities of a higher or competing priority." *TRAC*, 750 F.2d at 80. FDA is tasked with statutorily required activities affecting human and animal drugs, food, biologics, medical devices, and tobacco. Ganley Decl. ¶¶ 35-36. FDA has ordered its priorities and allocated its finite resources to these activities as it sees fit. The agency's decisions in this regard are entitled to "a presumption of regularity." *United States Postal Serv. v. Gregory*, 534 U.S. 1, 10 (2001).

Ordering FDA to fast track the outstanding portions of the monograph for topical antimicrobial drug products necessarily would interfere with the agency's other regulatory and enforcement activities. Courts traditionally refuse to impose this type of onus on administrative agencies. *See, e.g.*, *Barr Laboratories*, 930 F.2d at 72, 74, 76 ("[R]espect for the autonomy and comparative institutional advantage of the executive branch has traditionally made courts slow to assume command over an agency's choice of priorities . . . In short, we have no basis for reordering agency priorities."); *Fox*, 93 F. Supp. 2d at 547 ("Because a court is in general ill-suited to review the order in which an agency conducts its business, [the courts] are properly hesitant to upset an agency's priorities by ordering it to expedite one specific action, and thus to give it precedence over others." (quoting *Thomas*, 828 F.2d at 797) (internal quotation marks omitted)); *Liberty Fund, Inc. v. Chao*, 394 F. Supp. 2d 105, 117 (D.D.C. 2005) ("The Department's decision on how to handle competing applications is deserving of deference. . . . courts have declined to expedite action because of the impact on competing priorities.").

Nor is the fact that FDA's OTC Drug Review relates to human health and welfare determinative. For "this factor alone can hardly be considered dispositive when, as in this case, virtually the entire docket of the agency involves issues of this type." *Thomas*, 828 F.2d at 798; *see id.* ("[W]hether the public health and welfare will benefit or suffer from accelerating this particular rulemaking depends crucially upon the competing priorities that consume [the agency's] time, since any acceleration here may come at the expense of delay of [agency] action elsewhere.").

FDA's resources are limited, and the agency is currently engaged in a number of important regulatory efforts. Ganley Decl. ¶¶ 35-36. FDA's strategic priorities for 2011 through 2015 are available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/StrategicActionPlan/UCM226907.pdf. The Court should not second-guess FDA's "unique–and authoritative– position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way." *Barr Laboratories*, 930 F.2d at 76.

E. Plaintiff's Interests Are Not Prejudiced by the Alleged Delay

TRAC's fifth factor requires the Court to "take into account the nature and extent of the interests prejudiced by delay." *TRAC*, 750 F.2d at 80. NRDC will not be prejudiced by allowing the regulatory process to run its course. As discussed above, exposure to triclosan and triclocarban is avoidable because, as NRDC concedes, "substitute products are available." NRDC Br. at 23. NRDC argues that its members are prejudiced by FDA's alleged inaction because "[e]ach increment of exposure to triclosan and triclocarban increases the total body burden and risk to human health." This claim is unsubstantiated; FDA has not received data or information conclusively demonstrating that there is a known health risk from the level of

exposure to these active ingredients from existing drug products. Ganley Decl. ¶ 51; *see also Triclosan: What Consumers Should Know*, http://www.fda.gov/forconsumers/consumerupdates/ucm205999.htm (last accessed 11/15/10).

In contrast, the relief requested by NRDC would result in significant prejudice to other stakeholders—including the public and manufacturers of topical antimicrobial drugs.[16] *See United Steel Workers*, 783 F.2d at 1120 ("[E]ven were we to conclude that delay was unreasonable, judicial imposition of an overly hasty timetable at this stage would ill serve the public interest."). If FDA is required to finalize its 1994 TFM despite significant changes since its issuance, these stakeholders would be prejudiced by the lack of notice and opportunity to comment. *See Owner-Operator Indep. Drivers Ass'n Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 202 (D.C. Cir. 2007) (considering the "rule of prejudicial error" when "vacat[ing] an agency action [for procedure failure] during the notice-and-comment period") (internal quotation marks omitted). And FDA's final action would be vulnerable to being challenged and vacated. *See Crowley v. Fed. Bureau of Prisons*, 312 F. Supp. 2d 453, 458 (S.D.N.Y. 2004) ("It is well established that if a regulation has not been promulgated in proper compliance with the APA, that regulation is rendered invalid."); *United Steel Workers*, 783 F.2d at 1120 ("The rule ultimately promulgated by the agency, not to mention the agency's rationale for the rule must be construed carefully and thoroughly if the agency's action is to pass judicial scrutiny[.]").

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[16] In seeking a court order to compel FDA to finalize part of the ongoing OTC Drug Review, namely, the monograph for topical antimicrobial drug products, within 90 days, NRDC improperly seeks to curtail the processes and procedures in which FDA and interested persons have been engaged to issue scientifically sound monographs. *See, e.g., Sierra Club v. U.S. Army Corps of Engineers*, 702 F.2d 1011, 1042 (2d Cir. 1983), *cert. denied, NY State Dept. of Transp. v. Sierra Club*, 475 U.S. 1084 (1986) ("[E]xcept in the most extraordinary circumstances, the courts may not control the internal operations of federal administrative agencies."); *Maldonado-Coronel v. McElroy*, 943 F. Supp. 376, 386-87 (S.D.N.Y. 1996) ("[C]ourts have little power to shape an administrative agency's internal procedures.").

F. NRDC Has Not Alleged Impropriety, Nor Does Any Exist

Finally, the sixth and final factor—the existence of agency "impropriety"—does not favor NRDC. This is not a case in which the agency has been neglecting its duty to regulate antimicrobial drug products; rather, the agency has been steadily working towards finalizing the monograph for topical antimicrobial drug products. Given the evolving nature and complexity of the issues that require resolution prior to finalization, FDA's activities regarding the monograph have not been unreasonable. *See Fox*, 93 F. Supp. 2d at 548-49 (agency's "good faith . . . militates against intrusive equitable relief"); *see also Families for Freedom v. Napiltano*, 628 F. Supp. 2d 535 (S.D.N.Y. 2009).

CONCLUSION

Because plaintiff has failed to establish, based on the undisputed facts and clear application of the law, that this Court has jurisdiction over this matter or that plaintiff is entitled to the relief it seeks, the Court should enter judgment in favor of the government.

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